

REMARKS

Claims 10-12 and 14-20 currently are pending. No claim has been amended herein.

Claims 10-12 and 14, 17, 19 and 20 are rejected under 35 USC § 103(a) as being unpatentable over Guzi, Jr et al. (US 4,127,422). The examiner believes that even though the present claims differ from Guzi by reciting various concentrations of the active ingredients, the preparation of various compositions having various amounts of the active ingredients is within the level of ordinary skill in the art at the time of the invention. Also, the examiner believes it would have been obvious to follow the suggestions of the '422 reference to produce a dry excipient comprising a vinylpyrrolidone polymer and a nonionic surface-active agent by spray drying.

To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*see, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

None of the above requirements have been adequately shown by the examiner.

Guzi et al. refers to dry pigment compositions comprising 55 to 80% of a pigment and 45 to 20% of a nonionic material, which nonionic material is formed of a nonionic dispersing agent and a polymer such as polyvinylpyrrolidone. A homogeneous mixture of the pigment and the nonionic material is formed, which mixture is dried. Mixing can be performed by mixing the

components in one stage or by mixing the pigment in the presence of water with the nonionic dispersing agent followed by addition of the polymer (see col. 5, lines 22-29) and drying.

The examiner has argued that Guzi et al. teach the preparation of dry excipients. Applicants however, point out that in the dry pigment composition the pigment plays the role of the “active ingredient,” i.e., the ingredient that is to be formulated with the nonionic components so that stable aqueous dispersion of the pigment can be formed (col. 1, lines 10-17). According to Guzi et al., no dry excipients are formed, but formulations of the “active” pigment and excipients.

The present invention is directed to a process for preparing excipient compositions that do not contain an active ingredient. The innovation of the present invention lies in the liquid or semi-solid surface active substances that are otherwise difficult to handle (dues to their wax-like sticky behavior) are mixed with a specific polymer and then formed into a dry composition consisting solely of the surface-active substance and the polymer.

Therefore, Guzi et al. neither teaches nor suggests the each and every element of the present invention.

Claims 15 and 16 are rejected under 35 USC § 103(a) as being unpatentable over the combined disclosures of Guzi et al. ('422) and Shih et al. ('096) and Sutton et al. ('805). The examiner believes one of ordinary skill in the art would combine the surfactants of '096 into the process of '422, under its suggestion to improve the purity and stability. The examiner believes a skilled artisan would have been motivated to combine the surfactant of '805 into the process of '422 under its suggestions to improve the stability of the formulation. The examiner believes it

would have been obvious to one of ordinary skill in the art to combine the teachings and suggestions as such with an expected result of a spray dried excipient with improved stability and purity.

To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (see, e.g., *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

None of the above requirements have been adequately shown by the examiner.

Shi et al. ('096) relates to a process for polymerization of N-vinylpyrine polymers in the presence of a suspension agent, e.g., polyvinylpyrrolidone, and optionally also a water-soluble emulsifier to give an aqueous polyvinylpyridine suspension. From this aqueous suspension, the polyvinylpyridine can be recovered by filtering from the suspension and drying of the filtered polyvinylpyridine. Shih's teaching is directed at a process for making a polyvinylpyridine which is substantially pure and does not need to be separated from the suspension agents (see col. , lines 15-22). Therefore, Shih uses water-soluble suspension agent such as polyvinylpyrrolidone and water-soluble emulsifiers, so that the suspension agent and emulsifier stay within the aqueous phase from which the desired polyvinylpyridine polymer is filtered off and dried. Shih expressly provides for a process wherein the desired polymer product is substantially pure and does not contain the suspension agent. Since the water soluble emulsifier is used for entirely

different reasons one of ordinary skill in the art would not have been motivated to combine the surfactant of '096 into the formulation and process of '422.

Sutton et al. ('805) teach the formation of spray-dried hollow microcapsules comprising a pharmaceutical active ingredient together with e.g. polyvinylpyrrolidone and a surfactant. Combining Sutton's teaching with the formulation and the process from '422 does not lead to an excipient consisting essentially of a polymer and a surface active substance nor does it suggest the claimed process for making such excipients to improve handling of the surfact active substance.

Claim 18 is rejected under 35 USC 103(a) as being unpatentable over Guzi et al. and Kolter et al. The examiner believes that one of ordinary skill in the art would have been motivated to include the PVP composition of '769 into the process of '422 to improve the flow of the excipient and reduce agglomeration. Therefore, the examiner believes it would have been obvious to combine these teachings with an expected result of spray-dried excipient with improved flow and agglomeration properties.

To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (see, e.g., *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

The examiner has not pointed out anything in Kolter et al. that would teach or suggest the

fact that the present invention is directed to a process for preparing excipient compositions that do not contain an active ingredient. The innovation of the present invention lies in the liquid or semi-solid surface active substances that are otherwise difficult to handle (dues to their wax-like sticky behavior) are mixed with a specific polymer and then formed into a dry composition consisting solely of the surface-active substance and the polymer.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner and the rejection under 35 USC § 103 should be withdrawn.

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Respectfully submitted,

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